APPENDIX E

Vaccine Information Statements

It's Federal Law **E-1**

Instructions for Use of VISs **E-2**

How to Get Vaccine Information Statements **E-3**

VIS Questions and Answers **E-4**

CDC's Vaccine Information Statement Webpage **E-8**

Appendix E

It's federal law!

You must give your patients current Vaccine Information Statements (VISs)

A vaccine complication *in Florida highlights the importance of distributing the most recent VIS to your patients. In 1997, a 3-month-old boy developed vaccine-associated paralytic poliomyelitis (VAPP) following a first dose of OPV. The boy's parents reported that their physician furnished them with the 1994 polio VIS at the time of vaccination. The polio VIS had been revised in 1997 to reflect the ACIP preference for sequential use of inactivated polio vaccine (IPV), making the 1994 polio statement that was given to the parent outdated.*

Note: *the most current polio VIS carries the date of 1/1/00.*

To obtain a complete set of current VISs in up to 30 languages, visit IAC's website at www.immunize.org/vis.

This article was originally written by Neal A. Halsey, MD, director, Institute for Vaccine Safety, Johns Hopkins Bloomberg School of Public Health and was updated by the Immunization Action Coalition in November 2006.

As healthcare professionals understand, the risks of serious consequences following vaccines are many hundreds or thousands of times less likely than the risks associated with the diseases that the vaccines protect against. Most adverse reactions from vaccines are mild and self-limited. Serious complications such as the one in the Florida case are rare, but they can have a devastating effect on the recipient, family members, and the providers involved with the care of the patient. We must continue the efforts to make vaccines as safe as possible.

Equally important is the need to furnish vaccine recipients (or the parents/legal guardians of minors) with objective information on vaccine safety and the diseases that the vaccines protect against so that they are actively involved in making decisions affecting their health or the health of their children. When people are not informed about vaccine adverse events, even common, mild events, they can lose their trust in healthcare providers and vaccines. Vaccine Information Statements (VISs) provide a standardized way to present objective information about vaccine benefits and adverse events.

What are VISs?

VISs are developed by the staff of the Centers for Disease Control and Prevention (CDC) and undergo intense scrutiny by panels of experts for accuracy. Each VIS provides information to properly inform the adult vaccine recipient or the minor child's parent or legal representative about the risks and benefits of each vaccine. VISs are not meant to replace interactions with healthcare providers who should answer questions and address concerns that the recipient or the parent/legal representative may have.

Use of the VIS is mandatory!

Before a healthcare provider vaccinates a child or an adult with a dose of any vaccine containing diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, *Haemophilus influenzae* type b (Hib), varicella (chickenpox), influenza, or pneumococcal conjugate vaccine, the provider is required by the National Childhood Vaccine Injury Act (NCVIA) to provide a copy of the VIS to either the adult recipient or to the child's parent/legal representative.

VISs are also available for human papillomavirus (HPV), meningococcal, pneumococcal polysaccharide, and rotavirus, as well as various vaccines used primarily for international travelers. The use of these VISs is recommended but not currently required by federal law. (Editor's note: Use of VISs for HPV, meningococcal, and rotavirus vaccines will become mandatory at a later date.)

State or local health departments or individual providers may place the clinic name on the VISs, but any other changes must be approved by the director of CDC's National Center for Immunization and Respiratory Diseases.

What to do with VISs

Some of the legal requirements concerning the use of VISs are as follows:

1. Before an NCVIA-covered vaccine is administered to anyone (this includes adults!), you must give the patient or the parent/legal representative a copy of the most current VIS available for that vaccine. Make sure you give your patient time to read the VIS prior to the administration of the vaccine.
2. You must record in your patient's chart the date the VIS was given.
3. You must also record on the patient's chart the publication date of the VIS, which appears on the bottom of the VIS. As the Florida case above illustrates, it is imperative that you have the most current VIS.

Most current versions of VISs

As of November 2006, the most recent versions of the VISs are as follows:

DTaP/DT/DTP 7/30/01	PCV 9/30/02
hepatitis A 3/21/06	PPV 7/29/97
hepatitis B 7/11/01	polio 1/1/00
HPV (H. papillomavirus) 9/5/06	rabies 1/12/06
Hib 12/16/98	rotavirus 4/12/06
influenza (LAIV) ... 6/30/06	shingles 9/11/06
influenza (TIV) 6/30/06	Td 6/10/94
Japan. enceph. ... 5/11/05	Tdap 7/12/06
meningococcal 10/7/05	typhoid 5/19/04
MMR 1/15/03	varicella 12/16/98
yellow fever 11/9/04	

How to get VISs

VISs are available by calling your state or local health department. They also can be downloaded from the Immunization Action Coalition's website at www.immunize.org/vis or CDC's website at www.cdc.gov/nip/publications/vis.

Foreign language versions of VISs are not officially available from the CDC; however, several state health departments have arranged for their translations. These versions do not require CDC approval. You can find VISs in more than 30 languages on the Immunization Action Coalition's website at www.immunize.org/vis.

"We have an obligation to provide patients and/or parents with information that includes both the benefits and the risks of vaccines. This can be done with the Vaccine Information Statements that healthcare providers are required by law to provide prior to the administration of vaccines."

Walter A. Orenstein, MD, past director, National Immunization Program, CDC

Technical content reviewed by the Centers for Disease Control and Prevention, Nov. 2006.

www.immunize.org/catg.d/p2027law.pdf • Item #P2027 (11/06)

Instructions for the Use of
Vaccine Information Statements

Required Use

1. Provide VIS when vaccination is given.

As required under the National Childhood Vaccine Injury Act (42 U.S.C. §300aa-26), all health care providers in the United States who administer **to any child or adult** any vaccine containing diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A (use of hepatitis A VIS required effective July 1, 2006), hepatitis B, *Haemophilus influenzae* type b (Hib), trivalent influenza, pneumococcal conjugate, or varicella (chickenpox) vaccine shall, **prior to administration of each dose of the vaccine**, provide a copy to keep of the relevant current edition vaccine information materials that have been produced by the Centers for Disease Control and Prevention (CDC):

- to the parent or legal representative* of any child to whom the provider intends to administer such vaccine, and
- to any adult to whom the provider intends to administer such vaccine. (In the case of an incompetent adult, relevant VISs shall be provided to the individual's legal representative.* If the incompetent adult is living in a long-term care facility, all relevant VISs may be provided at the time of admission, or at the time of consent if later than admission, rather than prior to each immunization.)

If there is not a single VIS for a combination vaccine, use the VISs for all component vaccines.

The materials shall be supplemented with visual presentations or oral explanations, as appropriate.

*"Legal representative" is defined as a parent or other individual who is qualified under State law to consent to the immunization of a minor child or incompetent adult.

2. Record information for each VIS provided.

Health care providers shall make a notation in each patient's permanent medical record at the time vaccine information materials are provided indicating:
(1) the edition date of the Vaccine Information Statement distributed and
(2) the date the VIS was provided.

This recordkeeping requirement supplements the requirement of 42 U.S.C. §300aa-25 that all health care providers administering these vaccines must record in the patient's permanent medical record (or in a permanent office log):
(3) the name, address and title of the individual who administers the vaccine,
(4) the date of administration and
(5) the vaccine manufacturer and lot number of the vaccine used.

Applicability of State Law

Health care providers should consult their legal counsel to determine additional State requirements pertaining to immunization. The Federal requirement to provide the vaccine information materials supplements any applicable State laws.

Availability of Copies

Single camera-ready copies of the vaccine information materials are available from State health departments. Copies are also available on the Centers for Disease Control and Prevention's website at http://www.cdc.gov/nip/publications/VIS.
Copies are available in English and in other languages.

Current Editions of VISs

Diphtheria, Tetanus, Pertussis (DTaP/DT): 7/30/01
Haemophilus influenzae type b: 12/16/98
Hepatitis A: 3/21/06
Hepatitis B: 7/11/01
Inactivated Influenza: 6/30/06
Live, Intranasal Influenza: 6/30/06
Measles, Mumps, Rubella (MMR): 1/15/03
Pneumococcal conjugate: 9/30/02
Polio: 1/1/00
Tetanus Diphtheria (Td): 6/10/94
Varicella (chickenpox): 1/10/07

Reference 42 U.S.C. §300aa-26

1/17/07

CDC

How to Get Vaccine Information Statements

1. **The Internet.** All current VISs are available on the internet at two websites:

   - The National Immunization Program (www.cdc.gov/nip/publications/vis/default.htm)
   - The Immunization Action Coalition (www.immunize.org/vis/index.htm)

   VISs from these sites can be downloaded as pdf files and printed. You can also order single hard copies of the VISs using NIP's Online Order Form (at www.cdc.gov/nip/publications).

2. **State Health Department.** CDC sends each state health departments immunization program camerarady copies when a new VIS is published. The immunization program in turn provides copies to providers within the state.

A set of 7 **Videotapes** of VISs (MMR, DTP, Polio, Hepatitis B, Hib, Varicella, and Pneumococcal Conjugate) is available in English and Spanish from Michigan State University Extension. Tapes run approximately 59 minutes each, and a set costs $25. For information, call (517) 432-8204.

Audio files for most VISs can be downloaded from the National Immunization Program's VIS webpage (www.cdc.gov/nip/publications/vis/default.htm).

Text versions of the VISs can also be accessed from the National Immunization Program's VIS webpage. These files are compatible with screen-reader devices.

VIS **Translations** are available in more than 30 languages from the Immunization Action Coalition's website at www.immunize.org/vis/index.htm.

Arabic	French	Korean	Samoan
Armenian	German	Laotian	Serbo-Croatian
Bosnian	Haitian	Marshallese	Somali
Burmese	Hindi	Polish	Spanish
Cambodian	Hmong	Portuguese	Tagalog
Chinese	Ilokano	Punjabi	Thai
Croatian	Italian	Romanian	Turkish
Farsi	Japanese	Russian	Vietnamese

Questions & Answers: Vaccine Information Statements

1. Should the VISs be used for adults getting vaccines as well as for children?

Yes. Under the National Childhood Vaccine Injury Act, anyone receiving a covered vaccine should be given the appropriate VIS. VISs for vaccines that are administered to both adults and children are worded so they may be used by both.

2. Are VISs "informed consent" forms?

No. People sometimes use the term "informed consent" loosely when referring to VISs But even when vaccine information materials had tear-off sheets for parents to sign, they were not technical ly informed consent forms. The signature was simply to confirm that the "Duty to Warn" clause in the vaccine contract was being fulfilled.

There is no Federal requirement for informed consent. VISs are written to fulfill the information requirements of the National Childhood Vaccine Injury Act. But because they cover both benefits and risks associated with vaccinations, they provide enough information that anyone reading them should be adequately informed. Some states have informed consent laws, covering either procedural requirements (e.g., whether consent may be oral or must be written) or substantive requirements (e.g., types of information required). Check your state medical consent law to deter mine if there are any specific informed consent requirements relating to immunization. VISs can be used for informed consent as long as they conform to the appropriate state laws.

3. The law states that vaccine information materials be given to a child's legal representatives. Is this the same as "legal guardian?"

Not necessarily. A "legal representative" is a parent or other individual who is qualified under state law to consent to the immunization of a minor. It does not have to be the child's legal guardian (e.g., it could be a grandparent). There is not an overriding Federal definition.

4. Must the patient, parent, or legal representative physically take away a copy of each VIS, or can we simply let them read a copy and make sure they understand it?

Ideally the person getting the shot, or their representative, should actually take each VIS home. VISs contain information that may be useful later (e.g., the recommended vaccine schedule, information about what to do in the case of an adverse reaction). Patients may choose not to take the VIS, but the provider must offer them the opportunity to do so.

5. When do providers have to start using a new VIS?

The date for a new VISs required use is announced when the final draft is published in the Federal Register. Ideally, providers will begin using a new VIS immediately, particularly if the vaccine's contraindications or adverse event profile have changed significantly since the previous version.

6. How should we comply with the law for patients who cannot read the VISs (e.g., those who are illiterate or blind)?

The National Childhood Vaccine Injury Act requires providers to supplement the VISs with "visual presentations" or "oral explanations " as needed. If patients are unable to read the VISs, it is up to the provider to ensure that they have access to the information they contain. VISs can be read to these patients, or videotapes can be used as supplements. At least one CD-ROM is being produced on which users can hear the VIS's read. Audio files and versions of VISs that are compatible with screen reader devices are available on the NIP website.

7. Why are the dates on some of the VISs so old? Are they obsolete? Why can't they be updated every year?

VISs are updated only when they need to be. For instance, a VIS would be updated if there were a change in ACIP recommendations that affected the vaccine's adverse event profile, indications, or contraindications. If VISs were dated annually, there would be multiple editions in circulation that were identical but would have different dates. As it is, only the most recently-dated VIS for each vaccine is valid. VISs posted on the National Immunization Program's VIS webpage will always be current, regardless of the edition date.

8. Sometimes a VIS will contain a recommendation that is at odds with the manufacturer's package insert. Why?

VISs are based on the ACIP's recommendations, which occasionally differ from those made by the manufacturer. These differences may involve adverse events. Package inserts generally tend to include all adverse events that were temporally associated with a vaccine during clinical trials, whereas ACIP tends to recognize only those likely to be causally linked to the vaccine.

9. What is the reading level of VISs?

Defining the readibility of a VIS by a traditional "grade level" measure can be difficult and misleading. Two criteria used in standard readability formulas are word length and sentence length. Neither is necessarily a reliable measure of readability. There are multi-syllable words that are widely understood (e.g., "individual") and short words that are not (e.g., "spiv"). VISs often use bulleted lists, which a readability program might see as very long sentences (no period), even though they are actually quite easy to understand.

Applying a Fletch-Kincaid test to a VIS usually reveals about a 10th grade reading level, but this should be taken with the caveats in the preceding paragraph.

In what may be a more useful measure of readability, several VISs were the subject of a series of focus groups among low literacy parents in a variety of racial and ethnic groups (some not native English speakers) in 1998, and the participants overwhelmingly rated them easy to read and understand.

10. Which VISs must be used?

The appropriate VIS must be provided to the recipient of any vaccine covered by the National Childhood Vaccine Injury Act (NVCIA). As of November 2005, these VISs are DTaP, Td, MMR, Polio, Hepatitis B, Haemophilus influenzae type b (Hib), Varicella, Pneumococcal conjugate and Influenza vaccine. Final VISs for Hepatitis A and Tdap will be available soon, and meningococcal conjugate vaccine will soon be covered by the NVCIA.

VISs are available for all vaccines licensed in the United States (except BCG). Their use is strongly encouraged, whether it is mandated by the NCVIA or not.

11. May providers develop their own vaccine information materials or modify the VISs?

Providers who administer vaccines covered by the National Childhood Vaccine Injury Act are required to use the official CDC VISs. However, providers may supplement the VISs with materials of their own. Health departments or providers may add clinic name and contact information to a VIS as long as no other changes are made. Any other addition to these documents or variations from their language or format must have the prior written approval of the Director of CDC's National Immunization Program.

12. How should we distribute VISs when the parent or legal representative of a minor is not present at the time the vaccination is given, for example during a school-based adolescent vaccination program?

CDCs legal advisors have proposed two alternatives for this situation:

- *Consent Prior to Administration of Each Dose of a Series*. With this alternative the VIS must be mailed or sent home with the student around the time of administration of each dose. Only those children for whom a signed consent is returned may be vaccinated. The program must place the signed consent in the patient's medical record.

- *Single Signature for Series.* This alternative is permissible only in those States where a single consent to an entire vaccination series is allowed under State law and in those schools where such a policy would be acceptable. The first dose of vaccine may be administered only after the parent or legal representative receives a copy of the VIS and signs and returns a statement that a) acknowledges receipt of the VIS and provides permission for their child to be vaccinated with the complete series of the vaccine (if possible, list the approximate dates of future doses); and b) acknowledges their acceptance of the following process regarding administration of additional doses:

  Prior to administration of each dose following the initial dose, a copy of the VIS will be mailed to the parent (or legal representative) who signs the original consent at the address they provide on this statement, or the VIS will be sent home with the student; and

  The vaccine information statements for the additional doses will be accompanied by a statement notifying the parent that, based on their earlier permission, the next dose will be administered to their child (state the date), unless the parent returns a portion of this statement by mail to an address provided, to arrive prior to the intended vaccination date, in which the parent withdraws permission for the child to receive the remaining doses.

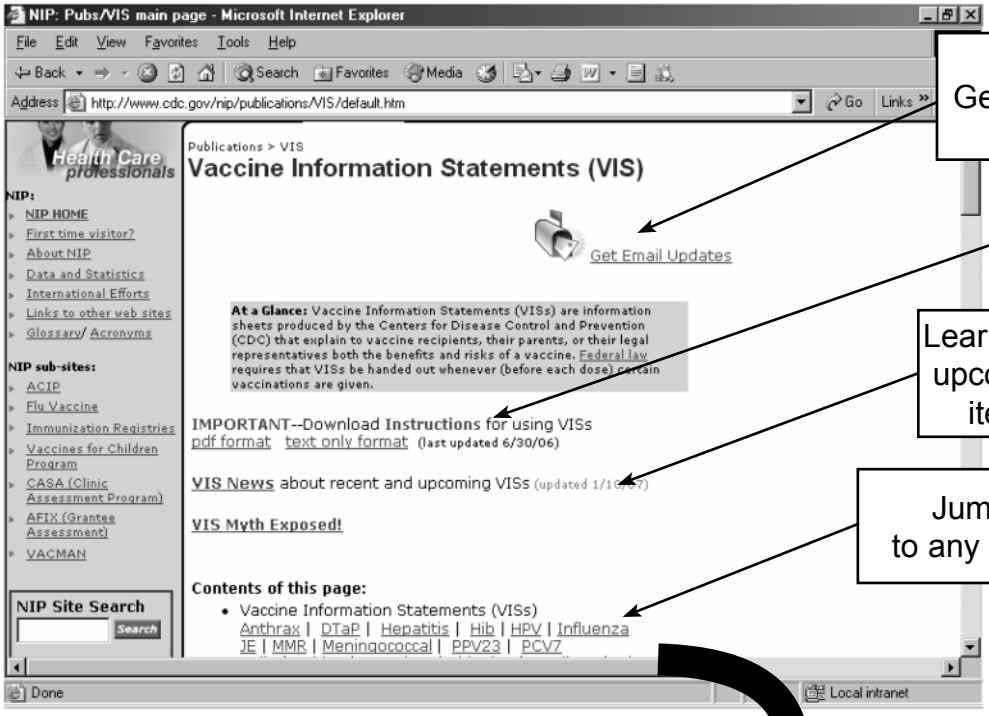
The program must maintain the original consent signature and any additional dose veto statements in the patient's medical record. A record must be kept of the dates prior to additional doses that the VIS was mailed, or sent home with the adolescent.

Prior to administration of each additional dose, the provider should ask the adolescent whether he/she experienced any significant adverse events following receipt of earlier doses. If yes, the provider should consider consulting the parent or delaying the vaccination. The adolescent's response to questions about adverse reactions to previous doses should be kept in the medical record.

Appendix E

CDC's Vaccine Information Statement Webpage

http://www.cdc.gov/nip/publications/VIS/default.htm

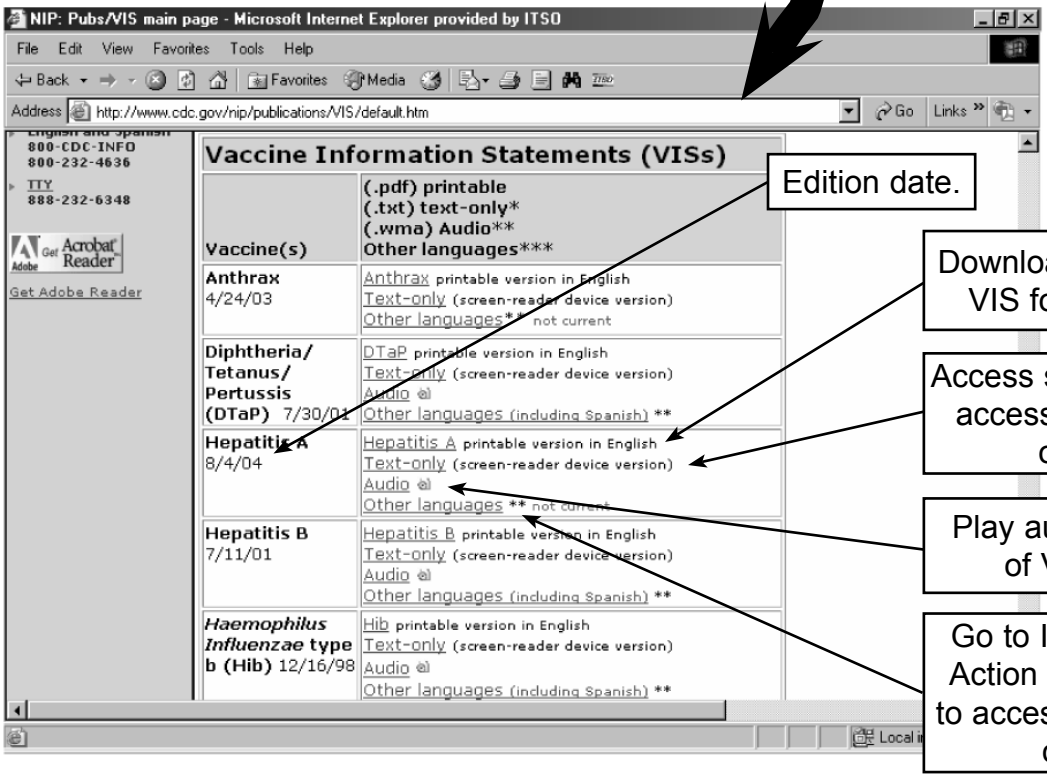


NEW
Get on mailing list for VIS updates.

Download VIS Instructions

Learn about new VISs, upcoming VISs, other items of interest.

Jump to any VIS.



Edition date.

Download pdf file of VIS for printing.

Access screenreader-accessible version of VIS.

Play audio file of VIS.

Go to Immunization Action Coalition site to access translations of VIS.